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Attorneys for Plaintiffs

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

(SAN FRANCISCO DIVISION)

CRB

IN RE: BEXTRA AND CELEBREX MARKETING SALES PRACTICES AND PRODUCT LIABILITY LITIGATION

MDL No. 1699

CLARITA BALDUGO, individually, SUSAN BAYLINK, individually, JANINE CAMPBELL, individually, VALERIE COATS, individually, WILMA CRAIG, individually, ROBERT HIGGINS, individually, WANDA PAYNE, individually, GENE REINDAHL, individually, RICK WOOD, as heir to decedent BEVERLY WOOD, THELMA ANDERSON, individually, EDWARD BARNES, individually, MURRY BARRETT, individually, PATRICIA BAVARDO, as heir to decedent MICHAEL BAVARDO, SALLY BYRO, individually, TIMOTHY CATON, as heir to decedent MICHAEL CATON, LOUISE CAVE, as heir to decedent CLIFFORD CAVE, SEDA DADAYAN, individually, UZUIMINDA GIBE, as heir to decedent GREGORIA DIAZ, ARTHUR FRIES, individually, UZUIMINDA GIBE, as heir to decedent AGAPITO GIBE, ELIZABETH HANCEY, as heir to decedent HELEN HANCEY, RITA JANOS, individually, JOSIF KAHRAMAN, as heir to decedent SUSAN KAHRAMAN, MYRTLE MASON, individually, DORTHY MAYFIELD, as heir to decedent CARLENIUS MAYFIELD, KAY MOORE, individually, GHOLAMALI MORADI, individually, LARRY NORMAN, SR., individually,

CV

Case No. 08 2252

CIVIL COMPLAINT

JURY TRIAL DEMANDED

ALEJANDRO PATRICIO, SR., individually, MICHAEL PRINCE, individually, PATRICIA REEVES, individually, NANCY ROTH, as heir to decedent HAROLD ROTH, CONSOLACION SAGISI, individually, JANE SEELEY, individually, KNARIK SHABOIAN, individually, CELIA SHIPMON, individually, VERNON SINN, individually, JOHN SMITH, individually, MICHAEL SPANGLER, individually, PATRICIA SQUALILIA, individually, JOHN STREMECKI, individually, TIMOTHY TOUCHETTE, individually, NEIL GUTMAN, as heir to decedent HAZEL WATSON, BEVERLY WHEELER, individually, BARBARA WIEMEYER, individually, MICHAEL WISE, individually, JANE ZYGAR, individually,

Plaintiffs,

v.

PFIZER, INC., PHARMACIA CORPORATION, and G.D. SEARLE LLC, (FKA G.D. SEARLE & CO.), and DOES 1 through 100,

Defendants.

CLARITA BALDUGO, individually, SUSAN BAYLINK, individually, JANINE CAMPBELL, individually, VALERIE COATS, individually, WILMA CRAIG, individually, ROBERT HIGGINS, individually, WANDA PAYNE, individually, GENE REINDAHL, individually, RICK WOOD, as heir to decedent BEVERLY WOOD, THELMA ANDERSON, individually, EDWARD BARNES, individually, MURRY BARRETT, individually, PATRICIA BAVARDO, as heir to decedent MICHAEL BAVARDO, SALLY BYRO, individually, TIMOTHY CATON, as heir to decedent MICHAEL CATON, LOUISE CAVE, as heir to decedent CLIFFORD CAVE, SEDA DADAYAN, individually, UZUIMINDA GIBE, as heir to decedent GREGORIA DIAZ, ARTHUR FRIES, individually, UZUIMINDA GIBE, as heir to decedent AGAPITO GIBE, ELIZABETH HANCEY, as heir to decedent HELEN HANCEY, RITA JANOS, individually, JOSIF KAHRAMAN, as heir to decedent SUSAN KAHRAMAN, MYRTLE

MASON, individually, DORTHY MAYFIELD, as heir to decedent CARLENIUS MAYFIELD, KAY MOORE, individually, GHOLAMALI MORADI, individually, LARRY NORMAN, SR., individually, ALEJANDRO PATRICIO, SR., individually, MICHAEL PRINCE, individually, PATRICIA REEVES, individually, NANCY ROTH, as heir to decedent HAROLD ROTH, CONSOLACION SAGISI, individually, JANE SEELEY, individually, KNARIK SHABOIAN, individually, CELIA SHIPMON, individually, VERNON SINN, individually, JOHN SMITH, individually, MICHAEL SPANGLER, individually, PATRICIA SQUALILIA, individually, JOHN STREMECKI, individually, TIMOTHY TOUCHETTE, individually, NEIL GUTMAN, as heir to decedent HAZEL WATSON, BEVERLY WHEELER, individually, BARBARA WIEMEYER, individually, MICHAEL WISE, individually, JANE ZYGAR, individually, hereinafter collectively referred to as "Plaintiffs", by and through their undersigned counsel, bring this action for damages against Defendants PFIZER, INC., PHARMACIA CORPORATION, and G.D. SEARLE LLC, (FKA G.D. SEARLE & CO.), and DOES 1 through 100 (hereafter "Defendants") for damages arising from Defendants' design, manufacture, sale, testing, marketing, advertising, promotion, and/or distribution of the unsafe prescription anti-inflammatory drugs Celebcoxib, trade name CELEBREX® ("CELEBREX") and Valdecoxib, trade name BEXTRA® ("BEXTRA").

PARTIES

PLAINTIFFS

CELEBREX PARTIES

1. Plaintiff THELMA ANDERSON, individually, was at all relevant times, an adult resident citizen of the State of Georgia and a resident of Dooly County, was prescribed CELEBREX and was severely injured as a result.

2. Plaintiff EDWARD BARNES, individually, was at all relevant times, an adult resident citizen of the State of North Carolina, and a resident of Robeson County, was prescribed CELEBREX, and was severely injured as a result.

3. Plaintiff MURRY BARRETT, individually, was at all relevant times, an adult resident citizen of the State of Tennessee, and a resident of Crockett County, was prescribed CELEBREX and was severely injured as a result.

4. Plaintiff SALLY BYRO, individually, was at all relevant times, an adult resident citizen of the State of Illinois, and a resident of DeKalb County, was prescribed CELEBREX, and was severely injured as a result.

5. Plaintiff SEDA DADAYAN, individually, was at all relevant times an adult resident citizen of the State of California, and a resident of Los Angeles County, was prescribed CELEBREX, and was severely injured as a result.

6. Plaintiff ARTHUR FRIES, individually, was at all relevant times an adult resident citizen of the State of California, and a resident of Orange County, was prescribed CELEBREX, and was severely injured as a result.

7. Plaintiff RITA JANOS, individually, was at all relevant times an adult resident citizen of the State of Mississippi, and a resident of Hinds County, was prescribed CELEBREX, and was severely injured as a result.

8. Plaintiff MYRTLE MASON, individually, was at all relevant times an adult resident citizen of the State of Alabama, and a resident of Walker County, was prescribed CELEBREX, and was severely injured as a result.

9. Plaintiff KAY MOORE, individually, was at all relevant times an adult resident citizen of the State of California, and a resident of San Bernardino County, was prescribed CELEBREX, and was severely injured as a result.

10. Plaintiff GHOLAMALI MORADI, individually, was at all relevant times an adult resident citizen of the State of California, and a resident of the Los Angeles County, was prescribed CELEBREX, and was severely injured as a result.

11. Plaintiff LARRY NORMAN, SR., individually, was at all relevant times an adult resident citizen of the State of Texas, and a resident of Harris County, was prescribed CELEBREX, and was severely injured as a result.

12. Plaintiff ALEJANDRO PATRICIO, SR, individually, was at all relevant times an adult resident citizen of the State of Hawaii, and a resident of Honolulu County, was prescribed CELEBREX, and was severely injured as a result.

13. Plaintiff MICHAEL PRINCE, individually, was at all relevant times an adult resident citizen of the State of California, and a resident of San Joaquin County, was prescribed CELEBREX, and was severely injured as a result.

14. Plaintiff PATRICIA REEVES, individually, was at all relevant times an adult resident citizen of the State of Texas, and a resident of Caldwell County, was prescribed CELEBREX, and was severely injured as a result.

15. Plaintiff CONSOLACION SAGISI, individually, was at all relevant times an adult resident citizen of the State of Hawaii, and a resident of Honolulu County, was prescribed CELEBREX, and was severely injured as a result.

16. Plaintiff JANE SEELEY, individually, was at all relevant times an adult resident citizen of the State of California, and a resident of Alameda County, was prescribed CELEBREX, and was severely injured as a result.

17. Plaintiff KNARIK SHABOIAN, individually, was at all relevant times an adult resident citizen of the State of New York, and a resident of Queens County, was prescribed CELEBREX, and was severely injured as a result.

18. Plaintiff CELIA SHIPMON, individually, was at all relevant times an adult resident citizen of the State of Florida, and a resident of Leon County, was prescribed CELEBREX, and was severely injured as a result.

19. Plaintiff VERNON SINN, individually, was at all relevant times an adult resident citizen of the State of Illinois, and a resident of DuPage County, was prescribed CELEBREX, and was severely injured as a result.

20. Plaintiff JOHN SMITH, individually, was at all relevant times an adult resident citizen of the State of Alabama, and a resident of Morgan County, was prescribed CELEBREX, and was severely injured as a result.

21. Plaintiff MICHAEL SPANGLER, individually, was at all relevant times an adult resident citizen of the State of Kentucky, and a resident of Pulaski County, was prescribed CELEBREX, and was severely injured as a result.

22. Plaintiff PATRICIA SQUAILIA, individually, was at all relevant times an adult resident citizen of the State of New York, and a resident of Saratoga County, was prescribed CELEBREX, and was severely injured as a result.

23. Plaintiff JOHN STREMECKI, individually, was at all relevant times an adult resident citizen of the State of California, and a resident of Alameda County, was prescribed CELEBREX, and was severely injured as a result.

24. Plaintiff TIMOTHY TOUCHETTE, individually, was at all relevant times an adult resident citizen of the State of Texas, and a resident of Tarrant County, was prescribed CELEBREX, and was severely injured as a result.

25. Plaintiff BEVERLY WHEELER, individually, was at all relevant times an adult resident citizen of the State of Colorado, and a resident of Adams County, was prescribed CELEBREX, and was severely injured as a result.

26. Plaintiff BARBARA WIEMEYER, individually, was at all relevant times an adult resident citizen of the State of California, and resident of Los Angeles County, was prescribed CELEBREX, and was severely injured as a result.

27. Plaintiff MICHAEL WISE, individually, was at all relevant times an adult resident citizen of the State of North Carolina, and resident of Cleveland County, was prescribed CELEBREX, and was severely injured as a result.

28. Plaintiff JANE ZYGAR, individually, was at all relevant times an adult resident citizen of the State of Oregon, and resident of Clackamas County, was prescribed CELEBREX, and was severely injured as a result.

29. The Plaintiffs identified in paragraph numbers 1 through 28 are hereinafter collectively referred to as the "CELEBREX Plaintiffs." Each of the aforementioned CELEBREX Plaintiffs was prescribed and ingested CELEBREX. Additionally, the CELEBREX Plaintiffs sustained serious injuries caused by ingesting CELEBREX.

BEXTRA PARTIES

30. Plaintiff CLARITA BALDUGO, individually, was at all relevant times, an adult resident citizen of the State of Hawaii and a resident of Ewa County, was prescribed BEXTRA, and was severely injured as a result.

31. Plaintiff SUSAN BAYLINK, individually, was at all relevant times an adult resident citizen of the State of Washington, and a resident of Cowlitz County, was prescribed BEXTRA, and was severely injured as a result.

32. Plaintiff JANINE CAMPBELL, individually, was at all relevant times an adult resident citizen of the State of California, and a resident of Orange County, was prescribed BEXTRA, and was severely injured as a result.

33. Plaintiff VALERIE COATS, individually, was at all relevant times an adult resident citizen of the State of Kansas, and a resident of Wyandotte County, was prescribed BEXTRA, and was severely injured as a result.

34. Plaintiff WILMA CRAIG, individually, was at all relevant times an adult resident citizen of the State of California, and a resident of Los Angeles County, was prescribed BEXTRA, and was severely injured as a result.

35. Plaintiff ROBERT HIGGINS, individually, was at all relevant times an adult resident citizen of the State of California, and a resident of Riverside County, was prescribed BEXTRA, and was severely injured as a result.

36. Plaintiff WANDA PAYNE, individually, was at all relevant times an adult resident citizen of the State of Georgia, and a resident of Stephens County, was prescribed BEXTRA, and was severely injured as a result.

37. Plaintiff GENE REINDAHL, individually, was at all relevant times an adult resident citizen of the State of Minnesota, and a resident of Lyon County, was prescribed BEXTRA, and was severely injured as a result.

38. The Plaintiff identified in paragraph numbers 30 through 37 are hereinafter referred to as the "BEXTRA Plaintiffs." Each of the aforementioned BEXTRA Plaintiffs was prescribed and ingested BEXTRA. Additionally, the BEXTRA Plaintiffs sustained serious injuries caused by ingesting BEXTRA.

WRONGFUL DEATH PARTIES

39. Plaintiff RICK WOOD, heir at law of decedent BEVERLY WOOD, was at all relevant times, an adult resident citizen of the State of Florida, and resident of Hillsborough County. Beverly Wood took BEXTRA and was injured as a result. Plaintiff RICK WOOD lost the care, comfort, companionship, affection and society of his mother as a result of her injuries.

40. Plaintiff, PATRICIA BAVARDO, heir at law of decedent MICHAEL BAVARDO, was at all relevant times, an adult resident citizen of the State of California, and a resident of Riverside County. Michael Bavardo took CELEBREX and was injured as a result. Plaintiff PATRICIA BAVARDO lost the care, comfort, companionship, affection and society of her husband as a result of his injuries.

41. Plaintiff TIMOTHY CATON, heir at law of decedent MICHAEL CATON, was at all relevant times, an adult resident citizen of the State of California, and a resident of San Joaquin County. Michael Caton took CELEBREX and was injured as a result. Plaintiff TIMOTHY CATON lost the care, comfort, companionship, affection and society of his brother as a result of his injuries.

42. Plaintiff LOUISE CAVE, heir at law of decedent CLIFFORD CAVE, was at all relevant times, an adult resident citizen of the State of California, and a resident of San Diego County. Clifford Cave took CELEBREX and was injured as a result. Plaintiff LOUISE CAVE lost the care comfort, companionship, affection and society of her husband as a result of his injuries.

43. Plaintiff UZUIMINDA GIBE, heir at law of decedent GREGORIA DIAZ, was at all relevant times, an adult resident citizen of the State of Hawaii, and a resident of Honolulu County. Gregoria Diaz took CELEBREX and was injured as a result. Plaintiff UZUIMINDA GIBE lost the care comfort, companionship, affection and society of her aunt as a result of her injuries.

44. Plaintiff UZUIMINDA GIBE, heir at law of decedent AGAPITO GIBE, was at all relevant times, an adult resident citizen of the State of Hawaii, and a resident of Honolulu County. Agapito Gibe took CELEBREX and was injured as a result. Plaintiff UZUIMINDA GIBE lost the care comfort, companionship, affection and society of her mother as a result of her injuries.

45. Plaintiff ELIZABETH HANCEY, heir at law of decedent HELEN HANCEY, was at all relevant times, an adult resident citizen of the State of Florida, and a resident of Hillsborough County. HELEN HANCEY took CELEBREX and was injured as a result. Plaintiff ELIZABETH HANCEY lost the care comfort, companionship, affection and society of her mother as a result of her injuries.

46. Plaintiff JOSIF KAHRAMA, heir at law to decedent SUSAN KAHRAMAN, was at all relevant times, an adult resident citizen of the State of Virginia, and a resident of Alexandria. SUSAN KAHRAMAN took CELEBREX and was injured as a result. Plaintiff JOSIF KAHRAMA lost the care, comfort, companionship, affection and society of his mother as a result of her injuries.

47. Plaintiff DOROTHY MAYFIELD, heir at law to decedent CARLENIUS MAYFIELD, was at all relevant times, an adult resident citizen of the State of Nevada, and a resident of Clark County. CARLENIUS MAYFIELD took CELEBREX and was injured as a result. Plaintiff DORTHY MAYFIELD lost the care, comfort, companionship, affection and society of her husband as a result of his injuries.

48. Plaintiff NANCY ROTH, heir at law to decedent HAROLD ROTH, was at all relevant times, an adult resident citizen of the State of California, and a resident of Orange County. HAROLD ROTH took CELEBREX and was injured as

a result. Plaintiff NANCY ROTH lost the care, comfort, companionship, affection and society of her husband as a result of his injuries.

49. Plaintiff NEIL GUTMAN, heir at law to decedent HAZEL WATSON, was at all relevant times, an adult resident citizen of the State of Texas, and a resident of Travis County. HAZEL WATSON took CELEBREX and was injured as a result. Plaintiff NEIL GUTMAN lost the care, comfort, companionship, affection and society of his mother in law as a result of her injuries.

50. The Plaintiffs identified in paragraphs 39 through 49 are hereinafter collectively referred to as the "Wrongful Death Plaintiffs." Each of the aforementioned Wrongful Death Plaintiffs are suing in their capacity as survivors and as representatives of the estates of the decedents identified above. The decedents were prescribed and ingested CELEBREX and/or BEXTRA. Additionally, the decedents sustained serious injuries caused by ingesting CELEBREX and/or BEXTRA.

DEFENDANTS

51. Defendant PFIZER, INC. ("PFIZER") is a Delaware corporation with its principal place of business in New York, New York. On July 16, 2002 PFIZER announced its proposed acquisition of PHARMACIA CORPORATION ('PHARMACIA"). On April 16, 2003, PFIZER completed its $60 billion acquisition of PHARMACIA. As a wholly-owned subsidiary of PFIZER, PHARMACIA acted in all aspects as PFIZER's agent and alter ego. At all relevant times, PFIZER and/or its predecessors in interest were engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling the drug Celecoxib, under the trade name CELEBREX, and the drug Valdecoxib, under the trade name BEXTRA in California and throughout the United States.

52. Defendant G.D. SEARLE LLC, (FKA G.D. SEARLE & CO.) ("SEARLE") is a Delaware corporation with its principal place of business in Illinois. In April 2000 SEARLE was acquired by PHARMACIA, and became a

wholly-owned subsidiary of PHARMACIA. At the time of PFIZER's acquisition of PHARMACIA, SEARLE was a wholly-owned subsidiary of PHARMACIA, acting as its agent and alter ego in all matters alleged in this Complaint, and is now a wholly-owned subsidiary of PFIZER. At all relevant times, SEARLE has been engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling the drug Celecoxib, under the trade name CELEBREX, and the drug Valdecoxib, under the trade name BEXTRA, in Connecticut, Texas, Utah, Mississippi, Missouri, New York, and California and throughout the United States.

53. Defendant PHARMACIA is a Delaware corporation with its principal place of business in New Jersey. PHARMACIA was created in April 2000 through the merger of Pharmacia & Upjohn with Monsanto Company and its G.D. SEARLE unit. PHARMACIA is now a wholly-owned subsidiary of PFIZER. At all relevant times, PHARMACIA, and its predecessors in interest have been engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling the drug Celecoxib, under the trade name CELEBREX, and the drug Valdecoxib, under the trade name BEXTRA, in Connecticut, Texas, Utah, Mississippi, Missouri, New York, and California and throughout the United States.

54. Celecoxib was developed in 1998 by SEARLE and marketed jointly by SEARLE and PFIZER under the brand name CELEBREX. SEARLE was acquired by PHARMACIA, which was then acquired by PFIZER, in part so that PFIZER could take full control of CELEBREX.

55. True names and capacities, whether individual, corporate, associate, or otherwise, of Defendants named herein as DOES 1 through 100, and each of them are unknown to Plaintiffs, who therefore sue said Defendants by such fictitious names.

56. Plaintiffs will ask leave to amend this Complaint to state said Defendants' true identities and capacities when the same have been ascertained.

57. Plaintiffs are informed and believe and based thereupon allege that each of the Defendants designated herein as DOE took part in and participated with the Defendants in all matters referred to herein and was in some manner responsible for the injuries and losses suffered by Plaintiffs.

58. At all times relevant to this action, Defendants intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the risks, dangers, defects, and disadvantages of CELEBREX and BEXTRA, and advertised, promoted, marketed, sold and distributed CELEBREX and/or BEXTRA as safe prescription medications when, in fact, Defendants had reason to know, and did know, that CELEBREX and BEXTRA were not safe for their intended purposes, for the patients for whom they were prescribed, and for whom they were sold; and that CELEBREX and BEXTRA caused serious medical problems, and in certain patients, catastrophic injuries and deaths.

59. In engaging in the conduct alleged herein, each Defendant acted as the agent for each of the other Defendants, or those Defendants' predecessors in interest.

JURISDICTION AND VENUE

60. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C.A. § 1332 (diversity jurisdiction). The amount in controversy exceeds $75,000.00 and there is complete diversity of citizenship between Plaintiffs and Defendants.

61. Venue is proper in this District pursuant to 28 U.S.C.A. § 1391. Defendants marketed, advertised and distributed the dangerous product in this district, thereby receiving substantial financial benefit and profits from sales of the dangerous product in this district, and reside in this district under 28 U.S.C.A. § 1391(c), such that venue is proper.

62. At all relevant times herein, Defendants were in the business of designing, manufacturing, marketing, developing, testing, labeling, promoting, distributing, warranting and selling their products, CELEBREX and BEXTRA.

Defendants at all times relevant hereto designed, developed, manufactured, promoted, marketed, distributed, tested, warranted and sold in interstate commerce (including Connecticut, Texas, Utah, Mississippi, Missouri, New York, and California) the aforementioned prescription drug. Defendants do substantial business in the State of California and within this District, advertise in this district, receive substantial compensation and profits from sales of CELEBREX and BEXTRA in this District, and made material omissions and misrepresentations and breaches of warranties in this District so as to subject them to *in personam* jurisdiction in this District. In engaging in the conduct alleged herein, each Defendant acted as the agent for each of the other Defendants or those Defendant's predecessors in interest.

INTERDISTRICT ASSIGNMENT

63. Assignment to the Northern District of California, San Francisco Division, is proper pursuant to MDL-1699, Pretrial Order No. 2 dated December 13, 2005, as this action is related to *In Re: Bextra and CELEBREX Marketing Sales Prac. and Pro. Liab. Lit.*, MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6, 2005.

FACTUAL BACKGROUND

OVERVIEW OF BEXTRA AND CELEBREX

64. BEXTRA (Valdecoxib) and CELEBREX (Celecoxib) are pharmaceutical treatments for musculoskeletal joint pain associated with osteoarthritis and rheumatoid arthritis among other maladies. Defendants Searle, Pharmacia, Monsanto and Pfizer did manufacture, design, package, market and distribute these drugs. Defendants Searle, Pharmacia and/or Pfizer (hereinafter "Defendants") encouraged the use of these drugs in improper customers, misrepresented the safety and effectiveness of these drugs and concealed or understated their dangerous side effects.

65. These Defendants aggressively marketed these drugs directly to the consuming public, although only available through prescription, through the use of

various marketing mediums, including, but not limited to, print and television advertisements. These Defendants did this to increase sales and profits.

66. The market for such pain relieving drugs is huge. BEXTRA was originally indicated for osteoarthritis, adult rheumatoid arthritis and pain. Approximately twenty million Americans suffer from osteoarthritis alone, while an additional two million suffer from rheumatoid arthritis.[1]

67. Defendants engaged in extensive advertising directed to consumer. For the period 2003 through 2004, BEXTRA brought in approximately $2 billion in revenue.[2]

68. At all times relevant hereto, the Defendants actually knew of the defective nature of their product as herein set forth, yet continued to design, manufacture, market, distribute and sell their products so as to maximize sales and profits at the expense of the general public's health and safety in conscious disregard of the foreseeable harm caused by these products. Defendants' conduct exhibits such an entire want of care as to establish that their actions were a result of fraud, ill will, recklessness, gross negligence or willful and intentional disregard to Plaintiffs' rights, and hence punitive damages are appropriate.

69. The damages sought herein are the direct and proximate result of Defendants' wrongful conduct in connection with designing, testing, inspecting, manufacturing, assembling, developing, labeling, sterilizing, licensing, marketing, advertising, promoting, selling, packaging, supplying and/or distributing the prescription drugs BEXTRA (Valdecoxib) and/or CELEBREX (Celecoxib).

70. At all times relevant hereto, Defendants were engaged in the business of designing, testing, inspecting, manufacturing, assembling, developing, labeling, sterilizing, licensing, marketing, advertising, promoting, selling, packaging, supplying and/or distributing the pharmaceutical drugs BEXTRA (Valdecoxib) and CELEBREX (Celecoxib) throughout the United States.

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[1] Statistics are from Centers for Disease Control and Prevention (CDC), National Institute of Arthritis and Musculoskeletal and Skin Diseases, part of the National Institutes of Health, and the Arthritis Foundation.

[2] Pfizer Annual Report to Shareholders, 2004.

71. Had Defendants properly disclosed the risks associated with using BEXTRA (Valdecoxib) and CELEBREX (Celecoxib), Plaintiffs would not have taken BEXTRA and/or CELEBREX (Celecoxib) for treatment of pain associated with Plaintiffs' injuries

FACTUAL ALLEGATIONS REGARDING CELEBREX

Facts Regarding Celebrex's Safety And Defendants' Knowledge Thereof

72. The potential for cardiovascular risk of selective COX-2 inhibitors was known to Defendants long before the FDA granted market approval in December 1998. By 1997, and prior to the submission of the New Drug Application (the "NDA") for CELEBREX, Defendants were aware that, by selectively inhibiting only the COX-2 enzyme, CELEBREX altered the homeostatic balance between prostacylcin synthesis and thromboxane and thereby increased the prothrombotic effects of the drugs, causing blood clots to form in those who ingested it.[3]

73. Pharmacologist Dr. Garrett Fitzgerald of the University of Pennsylvania reported in an editorial published in *The New England Journal of Medicine* on October 21, 2004, that contemporaneous with Defendants' launch it was known that selective COX-2 inhibitors, such as CELEBREX, suppressed the formation of prostaglandin I-2 in healthy volunteers, inhibited platelet aggregation in vitro, and may predispose patients to myocardial infarction or thrombotic stroke.[4]

74. Early FDA updates in March and April of 1999 similarly acknowledged this known risk, but noted, based upon PFIZER's representations, that CELEBREX "does not affect platelet aggregation (clumping), an important part of the blood clotting process."[5]

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[3] *See* Topol, E.J., *et al.*, "*Risk of Cardiovascular Events Associated with Selective Cox-2 Inhibitors*," JAMA, August 22, 2001 at 954.

[4] Fitzgerald, G.A., Patrono C., "*The Coxibs, Selective Inhibitors of Cyclooxygenase-2*," N Engl J Med 2001;345:433-442.

[5] *See* FDA Updates, *"New Arthritis Drug May Have Fewer Side Effects,"* FDA Consumer March-April 1999.

75. Based on the studies performed on CELEBREX, other COX-2 inhibitors, and basic research on this type of selective inhibitor which had been widely conducted, Defendants knew when CELEBREX was being developed and tested that selective COX-2 inhibitors posed serious cardiovascular risks for anyone who took them, and presented a specific additional threat to anyone with existing heart disease or cardiovascular risk factors.

76. Despite years of studies on selective COX-2 inhibitors, as well as the disturbing new studies specifically analyzing the risks of CELEBREX, Defendants failed to take any action to protect the health and welfare of patients, opting instead to continue promoting the drug for sale even after the FDA's Drug Safety and Risk Management Advisory Committee and Arthritis Drug Advisory Committee meetings.

Celebrex and Cox-2 Studies Did Not Show Celebrex to be Safe

Celebrex Long-Term Arthritis Safety Study (CLASS)

77. In September 1998, PHARMACIA sponsored an allegedly independent CELEBREX Long-Term Arthritis Safety Study ("CLASS"). The multicenter, double-blind, parallel group study sought to compare the incidence of clinically significant upper gastrointestinal events between CELEBREX 400 mg BID and Ibuprofen 800 mg.[6]

78. On September 13, 2000, Defendants released the results of the CLASS study in the *Journal of American Medicine.*[7] Researchers enthusiastically reported a "lower incidence of symptomatic ulcers and ulcer complications combined, as well as other clinically supported toxic effects, compared with NSAIDs at standard doses."

79. Although Defendants touted the CLASS study as the primary evidence to support its theory that CELEBREX was safer for consumers who could not

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[6] (CLASS data is found in NDA 20-998/S-009 submitted to the FDA by SEARLE on June 12, 2000. CLASS was submitted to the FDA on June 12, 2000 and reviewed by James Witter, M.D., Ph.D. (FDA Medical Officer) on September 20, 2000.)

[7] Silverstein, F.E., *et al.*, "*Gastrointestinal Toxicity with Celecoxib vs. Nonsteroidal Anti-inflammatory Drugs for Osteoarthritis and Rheumatoid Arthritis: The CLASS Study: A Randomized Controlled Trial,*" 284 JAMA 1247 (2000).

tolerate traditional NSAIDs in their gastrointestinal system, Defendants intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the results, risks and defects of the CLASS study. Among other things, Defendants failed to release the study's complete twelve month results releasing only the first six months of trials, reported biased and misleading results, limited conclusions to upper gastrointestinal events despite other known risks factors, and understated known cardiovascular risks.

80. Despite Defendants' favorable CLASS Study conclusions, no other reviewing or administrative body was able to substantiate those findings. The FDA Medical Officer Review of the CLASS data found CELEBREX to be no more efficacious than other traditional NSAIDS comparators.[8] According to the FDA's review of the CLASS data: "Celecoxib did not demonstrate any statistical superiority to NSAIDs (pooled) or either comparator (diclofenac and ibuprofen) with regards to the primary safety endpoint of CSUGIE (Clinically Significant Upper Gastrointestinal Adverse Events) at any point in the trial although there were trends that favored celecoxib." [9]

81. The FDA Arthritis Advisory Committee similarly found no "clinically meaningful" safety advantage of CELEBREX over older NSAIDs.[10] The CLASS Study failed to demonstrate a superior safety record over ibuprofen or pooled NSAID data. Based on this information, the Committee advised that further studies be done to assess the risk of COX-2 drugs and NSAIDS when taken with aspirin.

82. In a June 2002 editorial, the *British Medical Journal* chastised the Study's "misleading" and "seriously biased" nature; noting that the complete results "clearly contradict[ed] the published conclusions," and warning against the dangers of "overoptimistic," "short-term" data and "post hoc changes to the protocol."[11]

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[8] *See generally*, FDA Medical Officer Review, NDA 20-998/S-009 submitted to the FDA by SEARLE on June 12, 2000.

[9] FDA CLASS Review.

[10] FDA CDER Arthritis Advisory Committee, February 7th and 8th, 2001, Gaithersburg, Maryland.

[11] Juni, Peter, *et. at., "Are Selective COX 2 Inhibitors Superior To Traditional Non Steroidal Anti-Inflammatory Drugs?"* BMJ 2002;324:1287-1288.

Most noticeably, the CLASS study considered only six months of data despite the fact that researchers at that point had 12 months of data that, when analyzed as a whole, showed no significant difference. Instead of releasing the complete 12-month results from CLASS, PFIZER relied on and published only the first six months of data.[12] The results of the completed study revealed the real truth: CELEBREX offered no gastrointestinal (GI) benefit. Almost all ulcer-related complications that had occurred during the second half of the CLASS trials were in users of CELEBEX. These results clearly contradict the published CLASS conclusions.

83. Editors of the Journal of the American Medical Association (JAMA) and other medical experts were reportedly "flabbergasted" when they realized they had been "duped" by only being provided with the first six months of CLASS data.[13] The *Washington Post* reported JAMA editors noting: "When all of the data were considered, most of CELEBREX's apparent [GI] safety advantage disappeared."

84. Institutional bias also appeared to play a role in the Study's biased conclusions. According to the *Washington Post*, all sixteen CLASS authors were either employees of PHARMACIA or paid consultants of the company. Moreover, at least one author, Dr. M. Michael Wolfe, a gastroenterologist from Boston University, admits he was duped by PHARMACIA. In the summer of 2000, *The Journal of the American Medical Association* asked Wolfe to participate in the "six-month" trial. Wolfe found the study, tracking 8,000 patients over a six-month period, persuasive, and penned a favorable review, which helped to drive up CELEBREX sales. It was not until early the next year, while serving on the FDA's Arthritis Advisory Committee, that Wolfe learned the study had run for one year, not six months, as the company had originally led both Wolfe and the *Journal* to

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[12] JAMA 2000, 48:1455-1460.

[13] Okie, S., *"Missing data on Celebrex: Full study altered picture of drug,"* Washington Post 2001 Aug 5;Sect A:11.

believe.[14] Here again, when the complete data was considered, most of CELEBREX advantages disappeared.

85. Defendants also limited conclusions of the CLASS study to upper gastrointestinal events, despite other known risks factors, and understated known cardiovascular risks. A metastudy by the Cleveland Clinic published in the Journal of the American Medical Association analyzed data from two major studies, including CLASS, funded by the drug companies and two smaller ones—all for cardiovascular risks.[15] The metastudy found that PHARMACIA failed to identify and study cardiovascular risks for their products. The annualized heart attack rates for patients taking Vioxx or Celebrex, the researchers found, were "significantly higher" than those in a group taking placebos. "The available data raise a cautionary flag about the risk of cardiovascular events with Cox-2 inhibitors," they concluded.

86. "A total of 36 deaths occurred during the [CLASS] study or during post study follow-up: 19 in the celecoxib group, 9 in the diclofenac group and 8 in the ibuprofen group. . . . Most deaths were cardiovascular in nature."[16] The increased number of adverse cardiovascular events in the CELEBREX group was not surprising, as they were also revealed in the original New Drug Application (NDA) submitted for CELEBREX. "In the original NDA, myocardial infarction was noted to occur at a higher rate in celecoxib-treated as compared to placebo treated patients. In the long term trial (Trial 024) that was included in the NDA submission, the predominate (>90%) cause of death for patients taking celecoxib at any dose was cardiovascular."[17]

87. Public Citizen, a public watchdog organization, also reviewed the CLASS data in its entirety. A complete review reveals the combined anginal adverse events were 1.4% in the CELEBREX group versus 1.0% in either NSAID

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[14] *Id.*

[15] Debabrata Mukherjee, *et al.*, "*Risk of Cardiovascular Events Associated with Selective Cox-2 Inhibitors*," 286 JAMA 954 (2001).

[16] FDA CLASS Review at 54.

[17] FDA CLASS Review at 78.

group. Specifically, the rate of heart attack in the CELEBREX was double that of the other two NSAIDs, 0.2% vs. 0.1%, respectively.

88. Eric Topol of the Clevant Clinic reached a similar conclusion, noting that the CLASS trail MI rate was 1.6% in CELEBREX group (at a dosage of 400 mg twice a day) and 1.2% in the ibuprofen group for the 1739 patients taking low-dose aspirin. Topol noted that this numerical excess, albeit not statistically signification, was also found in the 6229 patients not taking aspirin in the trial.[18] Based on this data, Topol and his colleagues concluded: "It is mandatory to conduct a trial specifically assessing cardiovascular morbidity."[19] Unfortunately, no such trials were ever initiated, delaying the official warnings of CELEBREX and jeopardizing countless lives in the process.

89. The CLASS data proves that PFIZER knew that its first generation COX-2 inhibitor, CELEBREX, caused a disproportionately and statistically significant high number of adverse cardiovascular events before it was introduced to the market in January 1999. According to Public Citizen, after CLASS, the FDA recommended a trial to specifically assess the cardiovascular risks of COX-2 inhibitors. The Adenoma Prevention with Celecoxib (APC) trial was intended to be this placebo-controlled trial of CELEBREX.

APC Trial

90. In early 2000, the National Cancer Institute (NCI), in collaboration with SEARLE and PFIZER, initiated the Adenoma Prevention with Celecoxib (APC) trial, a randomized, double-blind, placebo-controlled study to discover the efficacy of CELEBREX in preventing the growth of pre-cancerous colon polyps.[20] The trial involved 2026 patients across the country with randomization to one of three groups: (1) placebo; (2) 200 mg CELEBREX twice daily; and (3) 400 mg CELEBREX twice daily. The patients, each of whom had an adenomatous polyp removed before enrollment, were followed up for a mean of 33 months while taking

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[18] Eric J. Topol, *"Arthritis Medicines and Cardiovascular Events – House of Coxibs,"* JAMA 293:366.

[19] *Id.*

[20] N.ENG. J. MED. 352;11 at 1072.

the study drug, with the primary objective of limiting the development of colorectal cancer.

91. On December 17, 2004, the National Cancer Institute suspended the use of CELEBREX for all participants in the APC trial due to "significant excess of cardiovascular death, myocardial infarction (MI) and stroke."[21] Analysis by an independent Data Safety Monitoring Board (DSMB) showed a two to three fold increased risk of major fatal and non-fatal cardiovascular events for participants taking the drug compared to those on a placebo with a secondary dose-response effect.

92. The absolute excess of major cardiovascular events of 13/1000 patients at the 800 mg dose (400 mg 2x day) was strikingly similar to the results of trials with rofecoxib and valdecoxib, both selective NSAID COX-2 inhibitors removed for the market for their significant cardiovascular risks.[22]

93. The FDA reported similar results, noting:

94. In the National Cancer Institute's Adenoma Prevention with Celecoxib (APC) trial in patients at risk for recurrent colon polyps, a 2-3 fold increased risk of serious adverse CV events was seen for CELEBREX compared to placebo after a mean duration of treatment of 33 months. There appeared to be a dose response relationship, with a hazard ratio of 2.5 for CELEBREX 200 mg twice daily and 3.4 CELEBREX 400 mg twice daily for the composite endpoint of death from CV causes, myocardial infarction (MI), or stroke.

95. April 7, 2005 FDA Alert: www.fda.gov/cder/drug/infopage/celebrex/celebrex-hcp.htm.

96. The dosage noted in the study is itself important for two reasons: first, there appears to be an association between dosage and the increase in adverse cardiovascular events; second, most patients increase dosage. PFIZER knew patients were increasing their dosages as noted in the CLASS Study: "Interestingly

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[21] Eric J. Topol, "*Arthritis Medicines and Cardiovascular Events – House of Coxibs,*" JAMA 293:366.

[22] Eric J. Topol, *"Arthritis Medicines and Cardiovascular Events – House of Coxibs,"* JAMA 293:366.

... up to 70% of patients increased their dose for celecoxib."[23] Thus, PFIZER was aware of "dosage creep."

Other CELEBREX Trials

97. Several other CELEBREX trials also gave Defendants insight into the cardiovascular risks presented by CELEBREX. The Prevention of Spontaneous Adenomatous Polyps (PreSAP) trial identified the death rate from cardiovascular causes (heart attack, stroke, heart failure, angina, or need for CV procedure) as 3.6% with CELEBREX as compared to 2.7% for placebo.

98. Public Citizen also reviewed the results of Study IQ IQ5-97-02-001 which reflected "the combined rate of all serious cardiovascular adverse events in patients getting a placebo was 2.1% but was greatly increased in those getting celecoxib to 7.7%, a 3.6 fold increase in CV risk in those people taking celecoxib. (p=0.03)."[24] According to Dr. Sidney Wolfe, "The study revealed a significantly increased rate (3.6-fold) of serious CV adverse events and more than a doubling in the rate of CV deaths in people using celecoxib compared to those using placebo."[25]

Cox-2 Studies: VIGOR and APPROVe

99. PFIZER also had access to other data which indicated a cardiovascular risk with its drugs. Specifically, PFIZER had knowledge of two studies conducted by Merck related to its Cox-2 inhibitor Vioxx – Vioxx Gastrointestinal Outcomes Research (VIGOR) and Adenomatous Polyp Prevention (APPROVe).

VIGOR

100. In 2000, The FDA Medical Officer Review of CLASS specifically noted the VIGOR trial and the concern over serious adverse cardiovascular events.[26]

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[23] FDA CLASS Review at 74.

[24] *Public Citizen*, January 26, 2005, Dr. Sidney M. Wolfe.

[25] *Id.*

[26] FDA CLASS Review at 78.

101. According to VIGOR (near acronym for Vioxx Gastrointestinal Outcomes Research) Vioxx patients experienced 20% more serious clinical adverse events (statistically significant); they experienced 4.6 times more hypertension events serious enough to warrant discontinuation, 1.7 times more edema events, and 1.85 times as many congestive heart failure adverse events. By two measures of cardiovascular events related to blood clots, Vioxx had twice the risk of naproxen and the results were considered statistically significant.

102. The VIGOR study comprised the most definitive scientific evidence ever obtained about pharmaceutical products. It was a large, randomized clinical trial, the gold standard of medical research. It was a safety study with endpoints set in advance. As Merck stated many times, it was designed to provide definite proof of safety, convincing enough to silence the most skeptical critics. In medical terms, the VIGOR results raised the question of whether selective inhibition of COX-2 was a monumental mistake from the start. While the NSAID risks to the GI system were real and sometimes fatal, they were dwarfed by the cardiovascular risks of the arthritis population that needed these drugs on a daily basis. All makers of NSAIDs, including Defendants, were aware of these results.

APPROVe

103. Anxious to put safety questions surrounding Vioxx to rest, Merck designed another large scale trial, Adenomatous Polyp Prevention (APPROVe), which was intended to test the drug's ability to prevent or shrink colon polyps, but would also compare the cardiovascular safety of Vioxx to a placebo control. According to the analysis conducted by Public Citizen of the APPROVe data: Vioxx "doubled the risk of any thrombotic cardiovascular event" and "doubled the risk of MI (myocardial infarction a/k/a heart attack)[27]. Although Merck claims that the two-fold risk of heart attacks and strokes seen in the APPROVe trial did not emerge until after patients had been taking the drug for 18 months, closer analysis indicates that significant increase in risk of heart attack was evident in as little as 4

[27] *Public Citizen, January 24, 2005, at 15.*

months time. Despite the available CELEBREX data and other information related to Vioxx, PFIZER never paused to reevaluate the CELEBREX data and studies.

104. The scientific data available during and after CELEBREX's approval process made clear to Defendants that their formulation of CELEBREX would cause a higher risk of blood clots, stroke and/or myocardial infarctions among CELEBREX consumers, alerting them to the need to do additional and adequate safety studies.

105. As stated by Dr. Topol on October 21, 2004, in *The New England Journal of Medicine*, outlining Defendants' failure to have conducted the necessary trials before marketing to humans "it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of (COX-2 inhibitors). Such a trial needed to be conducted in patients with established coronary artery disease, who frequently have coexisting osteoarthritis requiring medication and have the highest risk of further cardiovascular events."

106. Dr. Topol was also the author on the study published in August 2001 in JAMA (listed above) that reported an increased risk of thrombotic cardiovascular events in persons who used COX-2 inhibitors.

107. Based upon readily available scientific data, Defendants knew, or should have known, that their pre-approval testing of CELEBREX did not adequately represent the cross-section of individuals who were intended consumers and therefore, likely to take CELEBREX. Therefore, Defendants' testing and studies were grossly inadequate.

108. Had Defendants done adequate testing prior to approval and market launch, rather than the extremely short duration studies done on the small size patient base that was actually done, the Defendants' scientific data would have revealed significant increases in incidence of strokes and myocardial infarctions among the intended and targeted population of CELEBREX consumers. Adequate testing would have shown that CELEBREX possessed serious side effects. Defendants should have taken appropriate measures to ensure that their defectively

designed product would not be placed in the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made.

109. In fact, post-market approval data did reveal increased risks of clotting, stroke and myocardial infarction, but Defendants intentionally suppressed this information in order for them to gain significant profits from continued CELEBREX sales.

110. Defendants' failure to conduct adequate testing and/or additional testing prior to market launch was based upon their desire to generate maximum financial gains for themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

111. At the time Defendants manufactured, advertised, and distributed CELEBREX to consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding the increased risks of hypertension, stroke and/or myocardial infarctions because Defendants knew that if such increased risks were disclosed, consumers would not purchase CELEBREX, but instead would purchase other cheaper and safer NSAIDs.

Facts Regarding Defendants' Marketing And Sale Of CELEBREX

112. Such an ineffective and unreasonably dangerous drug could only be widely prescribed as a result of a tremendous marketing campaign. In addition to being aggressive, the Defendants' marketing campaign was fraudulent and misleading. But for fraudulent and misleading advertising, consumers, including the Plaintiff, would not have purchased CELEBREX, a more costly prescriptive drug, ineffective for its intended purposes.

113. Defendant's marketing was so fraudulent that the FDA issued three Warning Letters to Defendants in October 1999, April 2000, and November 2000, all finding that Defendants were unlawfully making false or misleading statements concerning the safety and/or efficacy of CELEBREX. The November letter cited two direct-to-consumer television advertisements that overstated the efficacy of

CELEBREX. The FDA ordered that SEARLE immediately cease distribution of the misleading ads.

114. On February 2001, the FDA issued a Warning Letter to PHARMACIA stating that promotional activities from marketing CELEBREX were unlawful because they were "false, lacking in fair balance, or otherwise misleading." The FDA found that CELEBREX had been promoted for unapproved uses, in unapproved dosing regiments, and that the marketers had made unsupportable claims that CELEBREX was safer and more effective than other NSAIDs.

115. In August 2001, it was revealed that PHARMACIA had misrepresented the results of a post-marketing clinical study of CELEBREX when submitting it for publication. PHARMACIA selectively omitted portions of the data relating to adverse effects. The *Washington Post* reported on August 5, 2001 that, "the study had lasted a year, not six months as . . . thought. Almost all of the ulcer complications that occurred during the second have of the study were in CELEBREX users. When all of the data were considered, most of CELEBREX's apparent safety advantage [as compared to traditional NSAIDs] disappeared."

116. On January 10, 2005 the FDA again issued PFIZER a written reprimand for its promotional activities. The reprimand reads: "These five promotional pieces [3 CELEBREX and 2 BEXTRA] variously: omit material facts … and make misleading safety, unsubstantiated superiority, and unsubstantiated effectiveness claims." Amid continued frustration with PFIZER's continually misleading marketing strategy and ever surmounting evidence of cardiovascular dangers, the FDA Advisory Panel voted overwhelmingly that the company should never again advertise the drug [CELEBREX]."

117. At all times relevant herein, Defendants engaged in a marketing campaign with the intent that consumers would perceive CELEBREX as a safer and better drug than its other NSAIDs and, therefore, purchase CELEBREX.

118. Defendants widely and successfully marketed CELEBREX throughout the United States by, among other things, conducting promotional campaigns that

misrepresented the efficacy of CELEBREX in order to induce a widespread use and consumption. CELEBREX was represented to aid the pain and discomfort of arthritis, osteoarthritis, and related problems. Defendants made misrepresentations by means of media advertisements, and statements contained in sales literature provided to Plaintiff's prescribing physicians.

119. Despite knowledge of the dangers presented by CELEBREX, Defendants and Defendants' predecessors in interest, through their officers, directors and managing agents for the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy the known defects of CELEBREX and failed to warn the public, including Plaintiff, of the serious risk of injury occasioned by the defects inherent in CELEBREX. Defendants and their officers, agents and managers intentionally proceeded with the inadequate safety testing, and then the manufacturing, sale and marketing of CELEBREX, knowing that persons would be exposed to serious potential danger, in order to advance their own pecuniary interests. Defendants' conduct was wanton and willful, and displayed a conscious disregard for the safety of the public and particularly of Plaintiffs.

120. In an elaborate and sophisticated manner, Defendants aggressively marketed CELEBREX directly to consumers and medical professionals (including physicians and leading medical scholars) in order to leverage pressure on third party payers, medical care organizations, and large institutional buyers (*e.g.*, hospitals) to include CELEBREX on their formularies. Faced with the increased demand for the drug by consumers and health care professionals that resulted from Defendants' successful advertising and marketing blitz, third party payers were compelled to add CELEBREX to their formularies. Defendants' marketing campaign specifically targeted third party payers, physicians, and consumers, and was designed to convince them of both the therapeutic and economic value of CELEBREX.

121. Defendants represented that CELEBREX was similar to ibuprofen and naproxen but was superior because it lacked any of the common gastrointestinal adverse side effects associated with these and other non-steroidal anti-inflammatory drugs ("NSAIDS"). Defendants promoted CELEBREX as a safe and effective alternative that would not have the same deleterious and painful impact on the gut, but that would be just as effective, if not more so, for pain relief.

122. Yet, CELEBREX possessed dangerous and concealed or undisclosed side effects, including the increased risk of serious cardiovascular events, such as heart attacks, unstable angina, cardiac clotting, deep vein thrombosis, hypertension, and cerebrovascular events, such as strokes. In addition, CELEBREX, which is significantly more expensive than traditional NSAIDs[28], was actually was no more effective than traditional and less expensive NSAIDs and, just like traditional NSAIDs, carried a risk of perforations, ulcers, and gastrointestinal bleeding. Yet, Defendants chose not to warn about these risks and dangers.

123. Defendants knew of these risks before the U.S. Food and Drug Administration (the "FDA") approved CELEBREX for sale, but Defendants ignored, downplayed, suppressed, omitted, and concealed these serious safety risks and denied inefficacy in its promotion, advertising, marketing, and sale of CELEBREX. Defendants' omission, suppression, and concealment of this important information enabled CELEBREX to be sold to, and purchased, or paid for by, the Consumers at a grossly inflated price.

124. Consequently, CELEBREX captured a large market share of anti-inflammatory drugs prescribed for and used by patients. In 2004 alone, sales of CELEBREX exceeded $2 billion, despite the significantly higher cost of CELEBREX as compared to other pain relievers in the same family of drugs.

125. Because Defendants engaged in a promotional and marketing campaign that featured an advertising blitz directly targeted to consumers, that touted CELEBREX as a safer drug than other drugs in its class, while uniformly

[28] The cost of Celebrex is at least $3-$6 per day, while an over-the-counter NSAID can cost $.50 or less per day.

failing to disclose the health risks of CELEBREX, Defendants were able to justify pricing CELEBREX significantly higher than the cost of generic aspirin. In reality, that price inflation was not justified. Had Defendants disclosed the truth about CELEBREX, Defendants would not and could not have reaped the billions of dollars in CELEBREX sales that were achieved as a direct result of the concealment, omission, suppression, and obfuscation of the truth.

126. The Defendants intentionally, deliberately, knowingly, and actively concealed, omitted, suppressed, and obfuscated important and material information regarding the risks, dangers, defects, and disadvantages of CELEBREX from Plaintiffs, the public, the medical community, and the regulators. This concealment and omission was deliberate, knowing, active, and uniform, was intended to induce and maximize sales and purchases of CELEBREX, and prevented Plaintiffs from obtaining all the material information that would be important to her decision as a reasonable person to purchase, pay for, and/or use CELEBREX.

127. Defendants' systematic, active, knowing, deliberate, and uniform concealment, omissions, suppression, and conduct caused Plaintiff to purchase, pay for, and/or use CELEBREX; and caused Plaintiffs' losses and damages as asserted herein.

128. Had Defendants done adequate testing prior to approval and "market launch," the defendants' scientific data would have revealed significant increases in stroke and myocardial infarction amongst the intended population of CELEBREX consumers. Adequate testing would have shown that CELEBREX possessed serious side effects. Defendants should have taken appropriate measures to ensure that their defectively designed product would not be placed in the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made.

129. In fact, post-market approval data did reveal increased risks of clotting, stroke and myocardial infarction, but Defendants intentionally suppressed

this information in order for them to gain significant profits from continued CELEBREX sales.

130. Defendants' failure to conduct adequate testing and/or additional testing prior to "market launch," and active concealment and failure to warn the medical community and general public of the known cardiovascular risks of CELEBREX was particularly negligent, reckless and/or malicious given the drug's known target market. Defendants were well aware that most patients taking CELEBREX are elderly and have higher risk of developing cardiovascular risks to begin with. Nearly half of the patients with arthritis have coexisting cardiovascular disease, and most patients, as discovered in the CLASS study, were prone to higher dosing.

131. Defendants' failure to conduct adequate testing and/or additional testing prior to "market launch" was based upon their desire to generate maximum financial gains for themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

132. At the time Defendants manufactured, advertising, and distributed CELEBREX to consumers including Plaintiffs, Defendants intentionally or recklessly ignored and/or withheld information regarding the increased risks of hypertension, stroke and/or myocardial infarctions because Defendants knew that if such increased risks were disclosed, consumers would not purchase CELEBREX, but instead would purchase other cheaper and safer NSAID drugs.

FACTUAL ALLEGATIONS REGARDING BEXTRA

133. BEXTRA (generically known as Valdecoxib) is second generation among the vaunted class of drugs called COX-2 inhibitors, which are touted as anti-inflammatory agents that cause less gastrointestinal damage than older, standby pain relievers like aspirin or ibuprofen. However, not only are their gastrointestinal benefits insignificant, they elevate the risk of heart attack. BEXTRA has a higher

level of COX-2 inhibition than its predecessor at Searle, Celebrex, and is substantially similar in inhibition levels to Merck & Co., Inc.'s drug, Vioxx®.

134. The Food and Drug Administration approved BEXTRA on November 19, 2001for the treatment of management of acute pain in adults, and for relief of the signs and symptoms of osteoarthritis and rheumatoid arthritis. Subsequent to FDA approval, BEXTRA was widely advertised and marketed by Defendants as a safe and effective pain relief medication.

135. BEXTRA is a member of a class of drugs known as "NSAIDs" (non-steroidal anti-inflammatory drug), but more specifically contains cyclooxygenase 2 ("COX-2") inhibitory properties. Generally, NSAIDs prevent the formation of fatty acid cyclooxygenases, of which there are two known types ("COX-1" and "COX-2"). BEXTRA is generally different than NSAIDs in that it is solely a COX-2 inhibitor. The rationale being that if the COX-1 enzyme is unaltered, the patient will experience fewer gastrointestinal complications commonly associated with NSAIDs. Further, the inhibition of COX-2 enzymes is said to decrease pain and inflammation.

136. In addition to the aforementioned, BEXTRA has been linked to several severe and life threatening medical disorders including, but not limited to, edema, changes in blood pressure, clotting, heart attack, stroke, seizures, kidney and liver damage, pregnancy complications, Stevens Johnson Syndrome and death. These known material risks were not disclosed to or shared with Plaintiff by Defendants.

137. Defendants' strategy during the pre-market approval process has been to aggressively market and sell its products by falsely misleading potential users about the products and by failing to protect users from serious dangers that Defendants knew or should have known to result from use of these products.

138. Defendants widely and successfully marketed BEXTRA in the United States, by undertaking an advertising blitz extolling the virtues of BEXTRA in order to induce widespread use of the products. The marketing campaign consisted of advertisements, promotional literature to be placed in the offices of doctors and

other health care providers, and other promotional materials provided to potential BEXTRA users.

139. The advertising program, as a whole, sought to create the image, impression and belief by consumers and physicians that the use of BEXTRA was safe for human use, had fewer side effects and adverse reactions than other pain relief medications and would not interfere with daily life, even though Defendants knew these to be false, and even though the Defendants had no reasonable grounds to believe them to be true.

140. Defendants purposefully downplayed and understated the health hazards and risks associated with BEXTRA. Defendants, through promotional literature, audio conferences, professional meetings, and press releases deceived potential users of BEXTRA by relaying positive information, including testimonials from satisfied users, and manipulating statistics to suggest widespread acceptability, while downplaying the known adverse and serious health effects. Defendants concealed material relevant information from potential BEXTRA users and minimized user and prescriber concerns regarding the safety of BEXTRA.

141. In particular, in the materials produced by Defendants, Defendants falsely misrepresented the severity, frequency and nature of adverse health effects caused by BEXTRA, and falsely represented that adequate testing had been conducted concerning BEXTRA.

142. Searle and its agents and/or representatives misrepresented claims regarding the efficacy of BEXTRA. In June 2003 Defendants completed a study that showed highly elevated risk for clotting, stroke and myocardial infarctions and had data from a second study by August 2004. The Defendants downplayed the significance of the negative cardiovascular thrombotic events in the studies as inconclusive as the studies were not long-term prospective randomized placebo controlled studies. According to Dr. Erick Topol, the need to conduct such long term studies prior to marketing this drug to humans was deemed "mandatory" and the patient population must include patients with both established cardiovascular

artery disease and osteoarthritis as this group has the highest risk of further cardiovascular complication. [29] Studies by Dr. Topol [30] and Dr. Garrett Fitzgerald [31] as early as 1999 showed that the inhibited platelet aggregation properties of Cox-2 inhibitors manifest itself in an increased risk of strokes and myocardial infarction.

143. Defendants' product promotion failed to present serious and significant risks associated with BEXTRA therapy for the intended population expected to take BEXTRA, which could and did result in increased risks of clotting, stroke and myocardial infarction.

144. As a result of the Defendants' advertising and marketing efforts, and representations concerning the subject products, BEXTRA was and continued to be pervasively prescribed throughout the United States, until it was voluntarily withdrawn from the market in April of 2005.

145. If Plaintiffs had known the risks and dangers associated with BEXTRA, Plaintiffs would not have taken BEXTRA and consequentially would not have been subject to its serious side effects.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Negligence

(Against All Defendants)

146. Plaintiffs incorporate by reference all of the paragraphs of this Complaint as if fully set forth herein.

147. Defendants owed Plaintiffs a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling CELEBREX and BEXTRA. This duty included the duty not to introduce pharmaceutical drugs, such as CELEBREX and BEXTRA, into the stream of

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[29] *The New England Journal of Medicine*, October 21, 2004.

[30] *Journal of the American Medical Association*, August 2001.

[31] *The New England Journal of Medicine*, October 21, 2004.

commerce that caused users to suffer from unreasonable, dangerous or untoward adverse side effects.

148. At all relevant times to this action, Defendants owed a duty to properly warn Plaintiffs and the Public of the risks, dangers and adverse side effects of their pharmaceutical drugs CELEBREX and BEXTRA.

149. Defendants breached their duties by failing to exercise ordinary care in the preparation, design, research, testing, development, manufacturing, inspection, labeling, marketing, promotion, advertising and selling of CELEBREX and BEXTRA, including:

(a) failing to use due care in the preparation and development of CELEBREX and BEXTRA to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

(b) failing to use due care in the design of CELEBREX and BEXTRA to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

(c) failing to conduct adequate pre-clinical testing and research to determine the safety of CELEBREX and BEXTRA;

(d) failing to conduct adequate post-marketing surveillance and exposure studies to determine the safety of CELEBREX and BEXTRA;

(e) failing to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiffs, consumers, the medical community, and the FDA;

(f) failing to accompany CELEBREX and BEXTRA with proper warnings regarding all possible adverse side effects associated with the use of CELEBREX and BEXTRA;

(g) failing to use due care in the manufacture, inspection, and

labeling of CELEBREX and BEXTRA to prevent the aforementioned risk of injuries to individuals who used CELEBREX and/or BEXTRA;

(h) failing to use due care in the promotion of CELEBREX and BEXTRA to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

(i) failing to use due care in the sale and marketing of CELEBREX and BEXTRA to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

(j) failing to use due care in the selling of CELEBREX and BEXTRA to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

(k) failing to provide adequate and accurate training and information to the sales representatives who sold CELEBREX and BEXTRA;

(l) failing to provide adequate and accurate training and information to healthcare providers for the appropriate use of CELEBREX and BEXTRA; and

(m) being otherwise reckless, careless and/or negligent.

150. Despite the fact that Defendants knew or should have known that CELEBREX and BEXTRA caused unreasonable and dangerous side effects which many users would be unable to remedy by any means, Defendants continued to promote and market CELEBREX and BEXTRA to consumers, including Plaintiffs, when safer and more effective methods of pain relief were available.

151. Defendants were, or should have been had they exercised reasonable care, in possession of evidence demonstrating that CELEBREX and BEXTRA caused serious side effects. Nevertheless, they continued to market their products by providing false and misleading information with regard to the safety and efficacy of CELEBREX and BEXTRA.

152. Defendants knew or should have known that consumers such as Plaintiffs would foreseeably suffer injuries as a result of their failure to exercise ordinary care as described above.

153. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiffs, sustained serious cardiovascular injuries; have required and/or will require healthcare and services; have incurred and will continue to incur medical and related expenses; have suffered loss of wages and a diminished capacity to earn wages in the future; have suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiffs' direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiffs will continue to incur such losses in the future.

154. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

155. WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

SECOND CLAIM FOR RELIEF

Strict Liability

(Against All Defendants)

156. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleged as follows:

157. At all times relevant to this action, Defendants were suppliers of CELEBREX and BEXTRA, placing the drug into the stream of commerce. CELEBREX and BEXTRA were expected to and did reach Plaintiffs without substantial change in the condition in which it was manufactured and sold.

158. CELEBREX and BEXTRA were unsafe for normal or reasonably anticipated use.

159. CELEBREX and BEXTRA were defective in design or formulation because when it left the hands of the manufacturer and/or supplier, they were unreasonably dangerous and more dangerous than an ordinary consumer would expect. CELEBREX and BEXTRA were also defective and unreasonably dangerous in that the foreseeable risk of injuries from CELEBREX and BEXTRA exceeded the benefits associated with the design and/or formulation of the products.

160. CELEBREX and BEXTRA are unreasonably dangerous: (a) in construction or composition; (b) in design; (c) because an adequate warning about the products was not provided; (d) because they do not conform to an express warranty of the manufacturer about the products.

161. CELEBREX and BEXTRA as manufactured and supplied by Defendants were also defective due to inadequate warnings, and/or inadequate clinical trials, testing and study, and inadequate reporting regarding the results of the clinical trials, testing and study. Defendants failed to perform adequate testing before exposing Plaintiffs to the medication, testing which would have shown that CELEBREX and BEXTRA had the potential to cause serious side effects including the injuries suffered like the Plaintiffs.

162. CELEBREX and BEXTRA as manufactured and supplied by Defendants were defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of injuries from CELEBREX and BEXTRA, they failed to provide adequate warnings to the medical community and the consumers, to whom they were directly

marketing and advertising CELEBREX and BEXTRA; and, further, it continued to affirmatively promote CELEBREX and BEXTRA as safe and effective.

163. CELEBREX and BEXTRA were manufactured, distributed, tested, sold, marketed, advertised and promoted defectively by Defendants, and as a direct and proximate cause of Defendants' defective designs of CELEBREX and BEXTRA, Plaintiffs used CELEBREX and/or BEXTRA rather than other safer and cheaper NSAIDs. As a result, Plaintiffs suffered the personal injuries described herein.

164. Information given by Defendants to the medical community and to the consumers concerning the safety and efficacy of CELEBREX and BEXTRA, especially the information contained in the advertising and promotional materials did not accurately reflect the potential side effects of CELEBREX and BEXTRA.

165. Had adequate warnings and instructions been provided, Plaintiffs would not have taken CELEBREX and/or BEXTRA, and would not have been at risk of the harmful side effects described herein.

166. Defendants acted with conscious and deliberate disregard of the foreseeable harm caused by CELEBREX and BEXTRA.

167. Plaintiffs could not, through the exercise of reasonable care, have discovered CELEBREX and BEXTRA's defects or perceived the dangers posed by the drug.

168. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, Plaintiffs, sustained serious cardiovascular injuries; have required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; have suffered loss of wages and a diminished capacity to earn wages in the future; have suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiffs' direct medical losses and costs include care for hospitalization, physician

care, monitoring, treatment, medications, and supplies. Plaintiffs will continue to incur such losses in the future.

169. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

170. WHEREFORE, Plaintiffs demand judgment against Defendants and seeks compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

THIRD CLAIM FOR RELIEF

Breach of Express Warranty

(Against All Defendants)

171. Plaintiffs incorporate by reference all of the paragraphs of this Complaint as if fully set forth herein.

172. Defendants expressly represented to Plaintiffs and other consumers and the medical community that CELEBREX and BEXTRA were safe and fit for their intended purposes, that they were of merchantable quality, that they did not produce any dangerous side effects, particularly any unwarned-of side effects, and that they were adequately tested.

173. These warranties came in the form of:

174. Defendants' public written and verbal assurances of the safety and efficacy of CELEBREX and BEXTRA;

175. Press releases, interviews and dissemination via the media of promotional information, the sole purpose of which was to create an increased demand for CELEBREX and BEXTRA, which failed to warn of the risk of injuries inherent to the ingestion of CELEBREX and/or BEXTRA, especially to the long-term ingestion of CELEBREX and/or BEXTRA;

176. Verbal and written assurances made by Defendants regarding CELEBREX and BEXTRA and downplaying the risk of injuries associated with the drugs;

177. False and misleading written information, supplied by Defendants, and published in the Physician's Desk Reference on an annual basis, upon which physicians relied in prescribing CELEBREX and BEXTRA during the period of Plaintiffs' ingestion of CELEBREX and BEXTRA, and;

178. Advertisements.

179. The documents referred to above were created by and at the direction of Defendants.

180. Defendants knew or had reason to know that CELEBREX and BEXTRA did not conform to these express representations in that CELEBREX and BEXTRA are neither as safe nor as effective as represented, and that CELEBREX and BEXTRA produce serious adverse side effects.

181. CELEBREX and BEXTRA did not and do not conform to Defendants' express representations because it is not safe, has numerous and serious side effects, including unwarned-of side effects, and causes severe and permanent injuries.

182. Plaintiffs, other consumers, and the medical community relied upon Defendants' express warranties.

183. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiffs, sustained serious cardiovascular injuries; have required and will require healthcare and services; have incurred and will continue to incur medical and related expenses; have suffered loss of wages and a diminished capacity to earn wages in the future; have suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiffs' direct medical losses and costs include care for hospitalization, physician

care, monitoring, treatment, medications, and supplies. Plaintiffs will continue to incur such losses in the future.

184. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

185. WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

FOURTH CLAIM FOR RELIEF

Breach of Implied Warranty

(Against All Defendants)

186. Plaintiffs incorporate by reference all of the paragraphs of this Complaint as if fully set forth herein.

187. Defendants manufactured, distributed, advertised, promoted, and sold CELEBREX and BEXTRA.

188. At all relevant times, Defendants knew of the use for which CELEBREX and BEXTRA were intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

189. CELEBREX and BEXTRA were not of merchantable quality and were not fit for their intended use, because they cause increased risk of serious cardiovascular and cerebrovascular adverse events, including heart attacks, strokes and other serious and harmful adverse health effects.

190. Defendants breached the implied warranty that CELEBREX and BEXTRA were of merchantable quality and fit for such use in violation of Md. Code Ann., Com. Law § 2-314, *et seq*.

191. Defendants were aware that consumers, including Plaintiffs, would use CELEBREX and/or BEXTRA for treatment of pain and inflammation and for other purposes.

192. Plaintiffs and the medical community reasonably relied upon Defendants' judgment and expertise to only sell them or allow them to prescribe CELEBREX and/or BEXTRA only if it was indeed of merchantable quality and safe and fit for its intended use. Consumers, including Plaintiffs, and the medical community, reasonably relied upon Defendants' implied warranty for CELEBREX and BEXTRA.

193. CELEBREX and BEXTRA reached consumers, including Plaintiffs, without substantial change in the condition in which they were manufactured and sold by Defendants.

194. Defendants breached their implied warranty to consumers, including Plaintiffs; CELEBREX and BEXTRA were not of merchantable quality or safe and fit for their intended use.

195. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiffs, sustained serious cardiovascular injuries; have required and will require healthcare and services; have incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; have suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiffs' direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiffs will continue to incur such losses in the future.

196. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive

and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

197. WHEREFORE, Plaintiffs demand judgment against Defendants and seeks compensatory damages and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

FIFTH CLAIM FOR RELIEF

Fraudulent Misrepresentation & Concealment

(Against All Defendants)

198. Plaintiffs incorporate by reference all of the paragraphs of this Complaint as if fully set forth herein.

199. Defendants' superior knowledge and expertise, their relationship of trust and confidence with doctors and the public, their specific knowledge regarding the risks and dangers of CELEBREX and BEXTRA, and their intentional dissemination of promotional and marketing information about CELEBREX and BEXTRA for the purpose of maximizing their sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material information about CELEBREX and BEXTRA's risks and harms to doctors and consumers.

200. Defendants made fraudulent affirmative misrepresentations with respect to CELEBREX and BEXTRA in the following particulars:

201. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that CELEBREX and BEXTRA had been tested and found to be safe and effective for the treatment of pain and inflammation; and

202. Defendants represented that CELEBREX and BEXTRA were safer than other alternative medications.

203. Defendants made affirmative misrepresentations; and fraudulently, intentionally and/or recklessly concealed material adverse information regarding the safety and effectiveness of CELEBREX and BEXTRA.

204. Defendants made these misrepresentations and actively concealed adverse information at a time when Defendants knew or had reason to know that CELEBREX and BEXTRA had defects and were unreasonably dangerous and were not what Defendants had represented to the medical community, the FDA and the consuming public, including Plaintiffs.

205. Defendants omitted, suppressed and/or concealed material facts concerning the dangers and risk of injuries associated with the use of CELEBREX and BEXTRA including, but not limited to, the cardiovascular, cerebrovascular, and other serious health risks. Furthermore, Defendants' purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of CELEBREX and/or BEXTRA in order to increase their sales.

206. The representations and concealment were undertaken by Defendants with an intent that doctors and patients, including Plaintiffs, rely upon them.

207. Defendants' representations and concealments were undertaken with the intent of defrauding and deceiving Plaintiffs, other consumers, and the medical community to induce and encourage the sales of CELEBREX and BEXTRA.

208. Defendants' fraudulent representations evinced their callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiffs.

209. Plaintiffs' physicians and Plaintiffs relied on and were induced by Defendants' misrepresentations, omissions, and/or active concealment of the dangers of CELEBREX and BEXTRA in selecting CELEBREX and/or BEXTRA treatment.

210. Plaintiffs and the treating medical community did not know that the representations were false and were justified in relying upon Defendants' representations.

211. Had Plaintiffs been aware of the increased risk of side effects associated with CELEBREX and BEXTRA and the relative efficacy of

CELEBREX and BEXTRA compared with other readily available medications, Plaintiffs would not have taken CELEBREX and/or BEXTRA as they did.

212. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiffs, sustained serious cardiovascular injuries; have required and will require healthcare and services; have incurred and will continue to incur medical and related expenses; have suffered loss of wages and a diminished capacity to earn wages in the future; have suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiffs' direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiffs will continue to incur such losses in the future.

213. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

214. WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

SIXTH CLAIM FOR RELIEF

Unjust Enrichment

(Against All Defendants)

215. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein.

216. At all times relevant to this action, Defendants were the manufacturers, sellers, and/or suppliers of CELEBREX and BEXTRA.

217. Plaintiffs paid for CELEBREX and/or BEXTRA for the purpose of managing their pain safely and effectively.

218. Defendants have accepted payment from Plaintiffs for the purchase of CELEBREX and/or BEXTRA.

219. Plaintiffs did not receive the safe and effective pharmaceutical product for which they paid.

220. It is inequitable and unjust for Defendants to retain this money because the Plaintiffs did not in fact receive the product Defendant represented CELEBREX and BEXTRA to be.

221. WHEREFORE, Plaintiffs demand judgment against Defendants and seeks equitable relief, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

SEVENTH CLAIM FOR RELIEF

Violations of State Consumer Fraud and Deceptive Trade Practices Acts

(Against All Defendants)

222. Plaintiffs incorporate by reference the preceding paragraphs as if they were fully set forth herein.

223. Defendants had a statutory duty to refrain from unfair or deceptive acts or practices in the sale and promotion of CELEBREX and/or BEXTRA to Plaintiffs.

224. Defendants engaged in unfair, unconscionable, deceptive, fraudulent and misleading acts or practices in violation of all California consumer protection laws, identified below. Through its false, untrue and misleading promotions of CELEBREX and BEXTRA, Defendants induced Plaintiffs to purchase and/or pay for the purchase of CELEBREX and/or BEXTRA. Defendants misrepresented the

alleged benefits and characteristics of CELEBREX and BEXTRA; suppressed, concealed and failed to disclose material information concerning known adverse effects of CELEBREX and BEXTRA; misrepresented the quality of CELEBREX and BEXTRA as compared to much lower-cost alternatives; misrepresented and advertised that CELEBREX and BEXTRA were of a particular standard, quality or grade that it was not; misrepresented CELEBREX and BEXTRA in such a manner that later, on disclosure of the true facts, there was a likelihood that Plaintiffs would have switched from CELEBREX and/or BEXTRA to another NSAID and/or chosen not to purchase and/or reimburse for purchases of CELEBREX and/or BEXTRA; advertised CELEBREX and BEXTRA with the intent not to sell them as advertised; and otherwise engaged in fraudulent and deceptive conduct.

225. Defendants' conduct created a likelihood of, and in fact caused, confusion and misunderstanding. Defendants' conduct misled, deceived and damaged Plaintiffs and Defendants' fraudulent, misleading and deceptive conduct was perpetrated with an intent that Plaintiffs rely on said conduct by purchasing and/or paying for purchases of CELEBREX and/or BEXTRA. Moreover, Defendants knowingly took advantage of Plaintiffs who were reasonably unable to protect their interests due to ignorance of the harmful adverse effects of CELEBREX and BEXTRA. Defendants' conduct was willful, outrageous, immoral, unethical, oppressive, unscrupulous, unconscionable and substantially injurious to Plaintiffs and offends the public conscience.

226. Plaintiffs purchased primarily for personal, family or household purposes.

227. As a result of Defendants' violative conduct, Plaintiffs purchased and/or paid for purchases of CELEBREX and/or BEXTRA that were not made for resale.

228. Defendants engaged in unfair competition or deceptive acts or practices in violation of HRS § 480-2, *et seq.*, among others.

229. As a proximate result of Defendants' misrepresentations and omissions, Plaintiff and Plaintiff have suffered ascertainable losses, in an amount to be determined at trial.

230. Throughout the period described in this Complaint, Defendants repeatedly engaged in intentional misconduct characterized by trickery, deceit and a wanton, willful, conscious and reckless disregard of the health, rights and interests of the Plaintiffs, and, in so conducting itself, acted with oppression, fraud, and malice toward the Plaintiff. As a result of Defendants' indifference to and reckless disregard of the health and safety of CELEBREX and BEXTRA patients, they suffered both physical and economic harm, and all end-payors incurred economic damages. Accordingly, Defendants' conduct was highly reprehensible under controlling Supreme Court punitive damages authority, and Plaintiffs are entitled to punitive and/or exemplary damages.

231. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiffs, sustained serious cardiovascular injuries; have required and will require healthcare and services; have incurred and will continue to incur medical and related expenses; have suffered loss of wages and a diminished capacity to earn wages in the future; have suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiffs' direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiffs will continue to incur such losses in the future.

232. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

233. WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

EIGHTH CLAIM FOR RELIEF

Wrongful Death

(Against All Defendants)

234. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein.

235. As a result of the conduct of Defendants and the ingestion of CELEBREX and/or BEXTRA by Plaintiffs' decedents, the decedents suffered fatal injuries.

236. Plaintiffs are the surviving heirs of the decedents. Defendants, and each of them, knew of the potential dangers and injuries related to CELEBREX/BEXTRA as stated herein. Defendants, and each of them, failed to warn of known dangers, were additionally negligent in their conduct toward decedent, breached warranties to decedent, concealed information and knowledge from decedent, negligently misrepresented information to decedent and violated various consumer statutes as described herein, all to the damage and detriment of Plaintiffs' decedent. Plaintiffs' decedent reasonably relied upon the skill, judgment, warranties, implied and express and upon Defendants' representations of safety and efficacy. As a direct and proximate result of Defendants' acts and omissions, Plaintiffs' decedent suffered injuries and, ultimately death. As a direct and proximate result of Defendants' acts and omissions, Plaintiffs have incurred medical and funeral expenses in an amount to be determined. Plaintiffs will seek leave to amend the complaint when such amount has been ascertained. As a direct and proximate result of Defendants' acts and omissions, Plaintiffs have been

deprived of the care, comfort, society and support of the decedent, all to Plaintiffs' future damage in a monetary sum to be determined at time of trial.

237. As a result of the death of the Plaintiffs' decedents, Plaintiffs were deprived of love, companionship, comfort, support, affection, society, solace and moral support of the decedents entitled to recover economic and non-economic damages against all defendants for wrongful death directly and legally caused by Defendants' product and the negligent acts, errors, omissions and intentional and negligent misrepresentations of Defendants and each of them.

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PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

1. General damages in excess of the jurisdictional amount of this Court;
2. Consequential damages;
3. Disgorgement of profits;
4. Restitution;
5. Punitive and exemplary damages;
6. Pre-judgment and post-judgment interest as provided by law;
7. Recovery of Plaintiffs' costs including, but not limited to, discretionary Court costs of these causes, and those costs available under the law, as well as expert fees and attorneys' fees and expenses, and costs of this action; and
8. Such other and further relief as the Court deems just and proper.

Dated: April 29, 2008

GIRARDI KEESE

By: _____
J. PAUL SIZEMORE
Attorney for Plaintiffs

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all claims so triable in this action.

Dated: April 29, 2008

GIRARDI KEESE

By: _____

J. PAUL SIZEMORE
Attorney for Plaintiffs

JS 44 (Rev. 12/07) (cand rev 1-16-08)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON PAGE TWO OF THE FORM.)

I. (a) PLAINTIFFS

CLARITA BALDUGO, individually (Please see attachment)

DEFENDANTS

PFIZER, INC., PHARMACIA CORPORATION, and G.D. SEARLE LLC, (FKA G.D. SEARLE & CO.), AND DOES 1 through 100,

(b) County of Residence of First Listed Plaintiff (EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant New York (IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

(c) Attorney's (Firm Name, Address, and Telephone Number)

Thomas V. Girardi, SBN 36603; J. Paul Sizemore, SBN 254981
V. Andre Sherman, SBN 198684; Jennifer A. Lenze, SBN 246858
Girardi Keese
1126 Wilshire Boulevard, Los Angeles, CA 90017 (213) 977.0211

Attorneys (If Known)

ADR
E-filing

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant) (For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury—Med. Malpractice
- ☒ 365 Personal Injury — Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities – Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus – Alien Detainee
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

08-2252 CRB

V. ORIGIN (Place an "X" in One Box Only)

☐ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☒ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (**Do not cite jurisdictional statutes unless diversity**):
Medical device products liability and wrongful death.

Brief description of cause:

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 **DEMAND $** CHECK YES only if demanded in complaint: **JURY DEMAND:** ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY **PLEASE REFER TO CIVIL L.R. 3-12 CONCERNING REQUIREMENT TO FILE "NOTICE OF RELATED CASE".** Judge Breyer - MDL 1699

IX. DIVISIONAL ASSIGNMENT (CIVIL L.R. 3-2) (PLACE AND "X" IN ONE BOX ONLY) ☒ SAN FRANCISCO/OAKLAND ☐ SAN JOSE

DATE
April 29, 2008

SIGNATURE OF ATTORNEY OF RECORD

J. PAUL SIZEMORE

ATTACHMENT TO CIVIL COVER SHEET
1. (a) PLAINTIFFS: (continued)

SUSAN BAYLINK, individually, JANINE CAMPBELL, individually, VALERIE COATS, individually, WILMA CRAIG, individually, ROBERT HIGGINS, individually, WANDA PAYNE, individually, GENE REINDAHL, individually, RICK WOOD, as heir to decedent BEVERLY WOOD, THELMA ANDERSON, individually, EDWARD BARNES, individually, MURRY BARRETT, individually, PATRICIA BAVARDO, as heir to decedent MICHAEL BAVARDO, SALLY BYRO, individually, TIMOTHY CATON, as heir to decedent MICHAEL CATON, LOUISE CAVE, as heir to decedent CLIFFORD CAVE, SEDA DADAYAN, individually, UZUIMINDA GIBE, as heir to decedent GREGORIA DIAZ, ARTHUR FRIES, individually, UZUIMINDA GIBE, as heir to decedent AGAPITO GIBE, ELIZABETH HANCEY, as heir to decedent HELEN HANCEY, RITA JANOS, individually, JOSIF KAHRAMAN, as heir to decedent SUSAN KAHRAMAN, MYRTLE MASON, individually, DORTHY MAYFIELD, as heir to decedent CARLENIUS MAYFIELD, KAY MOORE, individually, GHOLAMALI MORADI, individually, LARRY NORMAN, SR., individually, ALEJANDRO PATRICIO, SR., individually, MICHAEL PRINCE, individually, PATRICIA REEVES, individually, NANCY ROTH, as heir to decedent HAROLD ROTH, CONSOLACION SAGISI, individually, JANE SEELEY, individually, KNARIK SHABOIAN, individually, CELIA SHIPMON, individually, VERNON SINN, individually, JOHN SMITH, individually, MICHAEL SPANGLER, individually, PATRICIA SQUALILIA, individually, JOHN STREMECKI, individually, TIMOTHY TOUCHETTE, individually, NEIL GUTMAN, as heir to decedent HAZEL WATSON, BEVERLY WHEELER, individually, BARBARA WIEMEYER, individually, MICHAEL WISE, individually, JANE ZYGAR, individually,